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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/566,826	01/31/2006	Akio Kimura	06067/HG	8012

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EXAMINER
VU, JAKE MINH

ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
03/15/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/566,826	KIMURA ET AL.	
	Examiner	Art Unit	
	JAKE VU	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 September 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *8,9,12 and 14* is/are pending in the application.

4a) Of the above claim(s) *8 and 9* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12 and 14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of Applicant's Request for Continued Examination filed on 09/14/2010; and Amendment filed on 08/27/2010.

- Claim 12 has been amended.
- Claim 14 has been added.
- Claims 10-11 and 13 have been cancelled.
- Claims 8-9, 12 and 14 are pending in the instant application.
- Claims 8-9 have been previously withdrawn from consideration.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 09/14/2010 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 10-11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, pertaining to prostaglandin F2α with a fluorine atom derivatives, **are withdrawn** in view of Applicant's cancellation of the claims 10-11.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 12 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over MORISHIMA et al (WO 02/22131 published on 03/21/2002; wherein US 2004/0097592 is used as a translation) in view of KOIDE et al (JP 07-033650; translation provided).

Applicant's claims are directed to a product comprising of: prostaglandin F2α derivative having a fluorine atom, such as 16-phenoxy-15-deoxy-15,15-difluoro-17,18,19,20-tetranorprostaglandin F2α; a resin container formed from a polymer alloy of polyethylene terephthalate and polyarylate. Additional limitations include: liquid preparation; ratio of 1:2 to 2:1; inhibiting the decrease of the prostaglandin F2α derivative.

MORISHIMA teaches a product comprised of: prostaglandin F2α derivative having a fluorine atom, such as 16-phenoxy-15-deoxy-15,15-difluoro-17,18,19,20-

tetranorprostaglandin F2α (see US 2004/0097592 at [0024]); nonionic surfactant, such as polysorbate 80 (see [0004]); a resin container, such as a polymer of polyethylene terephthalate or acrylic resin (see [0014]). Additional disclosures include: ophthalmic solution (see [0001]), which reads on liquid preparation; inhibiting the active ingredient to be adsorbed to a resinous container (see abstract).

MORISHIMA does not specifically teach a resin container containing a copolymer of polyethylene terephthalate AND polyarylate with a ratio of 1:2 to 2:1.

KOIDE teaches using a resin container containing polyethylene terephthalate AND polyarylate (see translation at [0009]) for eye drop solutions containing nonionic surfactant (see [0006]). Additional disclosures include: the resin inhibits photolysis of the active ingredient (see [0001]) and inhibits the transference and adhesion of the active ingredient to the container (see [0002]); thus inhibiting the decrease of the active ingredient (see [0003]), which is the same objective as MORISHIMA and Applicant's claimed invention.

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to incorporate MORISHIMA's ophthalmic product into KOIDE's resin container containing a polymer alloy of polyethylene terephthalate AND polyarylate. The person of ordinary skill in the art would have been motivated to make those modifications, because it is known that the resin container inhibits photolysis of ophthalmic drug and inhibits the transference and adhesion of the drug to the container; thus inhibiting the decrease of the active drug. The person of ordinary skill in the art reasonably would have expected success because both reference dealt with inhibiting

the decrease of active agents in eye drop formulation using non-ionic surfactant and resin containers.

The references do not specifically teach adding the ingredients in the ratio amount as claimed by Applicant. The amount of a specific ingredient in a polymer is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ and reasonably would expect success. It would have been customary for an artisan of ordinary skill to determine the optimal amount of ratio in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of Applicant's invention.

Response to Arguments

Applicant argues that Morishima et al. reference (WO 02/22131) discloses an invention which focuses on additives of an eye drop, and discloses that the absorption of prostaglandin derivatives on a resin container can be inhibited by adding an additive (polysorbate 80 or ethylenediamine-tetraacetate) to an eye drop comprising prostaglandin derivatives. Whereas the presently claimed invention is characterized in using a polymer alloy of polyethylene terephthalate and polyarylate in a particular ratio range as a material for a container for an eye drop to inhibit a decrease of the content of specific prostaglandin F2a derivatives. The Koide et al. reference (JP 7-33650) is characterized in that vitamin A is contained in a container made of polyethylene

terephthalate, containing a pigment or pigments and a U-polymer (polyarylate), to inhibit the migration of vitamin A, which is unstable in light. Thus, since the container of Koide et al. (JP 7-33650) includes vitamin A, whereas the container of the presently claimed invention includes 16-phenoxy-15-deoxy-15,15-difluoro-17,18,19,20-tetranorprostaglandin F2alpha, it is clear that the chemicals in the respective containers include compounds that have completely different chemical structures and chemical properties. Furthermore, Koide et al. describe in paragraph [0008] that the fourth essential constituent of Koide et al. is a pigment which may have a high light shielding effect, such as tinuvin or anthraquinone yellow dye. Koide et al. also disclose that when the light shielding wavelength is less than 380nm, even after the addition of the pigment, the vitamin A therein decreases significantly after a long period.

Moreover, as is clear from Table 2 of Koide et al. (JP 7-33650), although Comparative Example 4 includes polyethylene terephthalate and a U-polymer as materials of a container, the concentration (residual ratio) of vitamin A is merely 26%. Considering that Koide et al. describe the comparison as an example, wherein no stabilizing effect of vitamin A is exhibited, it is respectfully submitted that from the disclosure of Koide et al., one of ordinary skill in the art would not consider to replace the vitamin A of Koide et al. with 16-phenoxy-15-deoxy-15,15-dif1uoro-17,18,19,20-tetranorprostagland F2 alpha.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir.

1986). In this case, the primary reference teaches Applicant's prostaglandin F2α derivative and the secondary reference teaches the Applicant's resin container formed from a polymer alloy of polyethylene terephthalate and polyarylate, wherein the resin container protects the ophthalmic drug. It would have been obvious to one skilled in the art to place the prostaglandin derivative into the resin container, since it is known that the resin container inhibits photolysis of the ophthalmic drug and inhibits the transference and adhesion of the drug to the container; thus inhibiting the decrease of the active drug, which is the same objective as Applicant's claimed invention.

Telephonic Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAKE VU whose telephone number is (571)272-8148. The examiner can normally be reached on Mon-Tue and Thu-Fri 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jake M. Vu/
Primary Examiner, Art Unit 1618